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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,149	04/26/2000	Nicholas Nicolaides	01107.00004	1171

7590 06/06/2003

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[REDACTED] EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	19

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/558,149	NICOLAIDES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 April 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13,14,18-20,29,52,53 and 58-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13,14,18-20,29,52,53 and 58-68 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The response and amendment filed 4-22-03 have been received and entered.
2. New claims 63-68 have been entered.
3. Claims 13, 14, 18-20, 29, 52, 53, and 58-68 are pending.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13, 14, 18-20, 29, 52, 53, and 58-62 remain rejected and claims 63-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record set forth in the previous office actions of 7-5-01, 3-26-02 and 12-18-02.

### ***Response to Arguments***

Applicant's arguments filed 4-22-03 have been fully considered but they are not persuasive. Applicants have argued that the specification describes the claimed hypermutable animals including their phenotype. Applicants have indicated to page 9, 7, 13 and 17 of the specification for support, however, none of these sections of the specification teach a phenotype and identifying characteristics of the broad genus of mammals encompassed by the claimed invention. It is noted that the supplementary declaration by Kline provides support for a transgenic mouse whose genome comprises the truncated mismatch repair gene PMS2 of SEQ ID NO 1, the specification does not provide sufficient written support for other species.

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encompassed by the claimed invention, particularly in view of the unpredictability of the art of making different species of a transgenic mammal using the same vector construct and method as discussed in the previous office action. It is emphasized that describing the gene comprised in the transgenic animal or structure of the gene does not provide written support for the characteristics produced in a transgenic mammal due to the expression of the gene which is unpredictable.

6. Claims 13, 14, 18-20, 29, 52, 53, and 58-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse in whose germ and somatic cells a mismatch repair gene PMS2 is integrated, wherein said PMS2 gene comprises the sequence disclosed in SEQ ID NO 1 and wherein the tissue of said transgenic mouse have defect in mismatch repair and a method of making said transgenic mouse, does not reasonably provide enablement for other embodiments of the claimed invention for reasons of record set forth in the previous office actions of 7-5-01, 3-26-02 and 12-28-02. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

***Response to Arguments***

Applicant's arguments filed 4-22-03 have been fully considered but they are not persuasive to obviate all the grounds of rejection. In view of the supplementary declaration by J. Bradford Kline, the total lack of enablement rejection of the pending claims has been modified to a scope of enablement rejection because the two declarations by Kline provide the possession and enablement for a transgenic mouse as indicated in the scope rejection and discussed below and therefore the rejection has been withdrawn with respect to making and using of a transgenic mouse as indicated in the enablement rejection above. However, the making and using of any transgenic mammal is maintained for reasons of record. Applicants have argued that the methods of making transgenic mice and cattle were known prior to the effective filing date of the application and

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they have attached five articles in support of their arguments. Applicants argue that Bremel et al (US Patent 6,080,912), Deboer et al (US Paten 6,140,552) teach production of transgenic cattle whereas Sun et al US patent 6,339,183, Bujard et al (US Patent 5,912,411) and Houbedine et al (US 5,965,788). However, these patents teach specific animals and do not address the unpredictability issues discussed in the previous office actions. Regarding the declaration, the teachings of the declaration only teaches making a transgenic mouse and not a transgenic mammal and does not address the issues of unpredictability as discussed in the previous office actions. Regarding applicants arguments pertaining to the how to use of the transgenic mammals, the specification does not teach how to use a transgenic mammal whose characteristics are not known and as discussed in the previous office actions, one can not predict what characteristics would be obtained in a transgenic mammal.

### ***Double Patenting***

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 29, 52, 53 and 58-61 remain provisionally rejected and claims 63-68 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13-18 and 45-50 of co-pending Application No. 09/853,645 for reasons of record set forth in the previous office action of 12-28-02. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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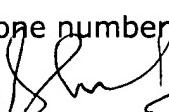
Applicants' request for abeyance of this rejection until indication of allowable claims is noted.

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM SHUKLA  
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632